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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,615	04/06/2001	William C. Olson	64672/JPW/SHS/NS	5850

7590

09/17/2004

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EXAMINER

STUCKER, JEFFREY J

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/828,615	Applicant(s) OLSON ET AL.	
	Examiner Jeffrey Stucker	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-30 and 32-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 and 32-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Office Action is in response to the amendment filed 25 June 2004. Claim 31 is canceled, claims 46-49 are added, and claims 23-30 and 32-49 are pending and under final rejection.

Applicant IDS and comments in regards to the IDS have been considered. Several comments are in order.

1) Only 3 US patents and 2 PGPubs documents have been provided to the Office. See attachment A, "ePheonix" page. All of the foreign patents have been provided.

2) Pages 21-23 are confusing and contradictory. For examples, see paragraphs marked C and D, among others, of attachment B. The reference numbers, as filed, are incorrect. Note that paragraph G seems to contradict corrected paragraph C. Paragraphs H, I, and J also seem to be incorrect. Clarification is required.

3) Only the references that have actually been provided to the Office have been considered. Because of the confusing nature of the remarks concerning the references in the IDS, citations to references which were not provided have been lined through. The lined-through references have been considered to the extent that they may be duplicates of the references provided.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claims 26 and 27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** in view of the showing of deposits under the terms of the Budapest Treaty.

The rejection of claims 23-25 and 28-45 under 35 U.S.C. 103(a) as obvious over Vila-Coro et al. (PNAS 3/00) **is withdrawn**.

The following are new grounds of rejection necessitated by applicant's submission of an information disclosure statement under with the appropriate fee.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1648

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 24, 48, 28, 29, 30, 32, and 33 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Allaway et al. US Patent 6,107,019.

The claimed invention is drawn to a methods of reducing HIV-1 load by administering an IgG antibody which binds to a CCR5 chemokine receptor and inhibits fusing of HIV-1 to CD4⁺CCR5⁺ cells. One of the embodiments is specifically directed to inhibiting HIV-1_{JR-FL}. The inhibition is set forth as being reduced by various percentages of at least 50%.

Allaway et al. teaches inhibiting HIV-1 in CD4⁺ cells by administering a non-chemokine agent capable of binding to a

Art Unit: 1648

chemokine receptor. The CCR5 receptor is specifically taught at column 5, lines 35-39, as well as several other places throughout the specification. The non-chemokine agent can be an antibody as disclosed at column 2, lines 39-42 and column 5, lines 65-67, as well as several other places throughout the specification. The embodiment of the HIV-1_{JR-FL} strain is taught throughout the patent.

The reference does not specifically teach that the antibody is IgG, but this is the predominant type of immunoglobulin so it would be expected that the antibody of the reference is also of the IgG isotype. If the antibody is not IgG, it would be obvious to produce an IgG antibody because IgG antibodies are easier to produce in large quantities than other isotypes. The specific amount of reduction in viral load is a description of the desired result and an inherent property of inhibiting viral infection. Thus, the claimed invention is obvious over Allaway et al.

Claims 23, 24, 48, 28, 29, 30, 32, and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Progenics Pharmaceuticals, Inc. (Progenics), WO 97/47319.

Art Unit: 1648

HIV-1_{JR-FL} gp120 to CCR5

HIV-1_{JR-FL}

Claims 23-30, 32-44, 48, and 49 are rejected under 35 U.S.C. 103(a) as obvious over Allaway et al. US Patent 6,107,019 or Progenics Pharmaceuticals, Inc. (Progenics), WO 97/47319.

The invention is further limited to various routes of administration, dosages, etc.

The routes of administration, dosages, etc., are routine to adjust and would be within the skill of the artisan to optimize the method. Thus, the instant specification is obvious over Allaway et al. US Patent 6,107,019 or Progenics Pharmaceuticals, Inc. (Progenics), WO 97/47319.

Claims 23, 24, 48, and 45-47 are rejected under 35 U.S.C. 103(a) as obvious over Allaway et al. US Patent 6,107,019 or Progenics Pharmaceuticals, Inc. (Progenics), WO 97/47319, each in view of Cruse et al.

The claimed invention is further limited to humanized or chimeric antibodies.

These types of antibodies are known in used in the art. See Cruse et al. One would be motivated to use these types of antibodies for the reasons given under "humanized antibody".

Art Unit: 1648

Thus, the claimed invention is obvious over Allaway et al. or Progenics, each in view of Cruse et al.

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 25 June 2004 prompted the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

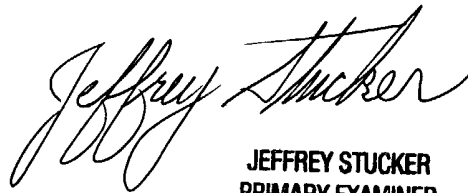
Art Unit: 1648

(PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.



JEFFREY STUCKER
PRIMARY EXAMINER